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September 24,2004

Margaret Efron, Patent Attorney

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT Patent Application Docket No. UF-368XC1 Serial No. 10/809,631

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Art Unit

1614

Applicant(s)

Nathan Andrew Shapira, Toby Doris Goldsmith, Pierre Martin Blier

Serial No.

10/809,631

Filed

March 24, 2004

For

Methods for Treating Idiopathic Hyperhidrosis and Associated Conditions

Mail Stop Amendment Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

## SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR §§1.97 AND 1.98

Sir:

In accordance with 37 C.F.R. §1.56, the references listed on the attached form PTO-1449 are being brought to the attention of the Examiner for consideration in connection with the examination of the above-identified patent application. Copies of the cited documents are enclosed.

The undersigned hereby certifies that each item of information contained in this statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this statement.

Two of the cited references in the International Search Report are in a foreign language; however, to meet the duty of disclosure, the applicants have also included a copy of the International Search Report showing the relevancy of each of these cited references. The cited references in a

- 1) WO 03/011340 A1, February 13, 2003; and
- 2) NL 1014289, August 7, 2001.

Please note that WO 03/011340 reference has an English abstract.

The applicants respectfully assert that the substantive provisions of 37 CFR §§1.97 and 1.98 are met by the foregoing statement.

Respectfully submitted,

Margaret Efron

Patent Attorney

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Gainesville, FL 32606-6669

MHE/la

Enclosure(s): Form PTO-1449;

Copies of cited references; and

Copy of International Search Report.

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PTO/SB/08A (08-00) Approved for use through 10/31/2002. OMB 0651-0031
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Sheet	1	of	2	Attorney Docket Number	UF-368XC1			

	U.S. PATENT DOCUMENTS						
Examiner Initials*	Cite No. <sup>1</sup>		ent Code <sup>2</sup> known)	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	
	U1	US 2002/103206	A1_	Berendsen	08-01-2002	ALL	
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	FOREIGN PATENT DOCMENTS								
Examiner Initials*	Cite No. 1	Fore	gn Patent Docum Number <sup>4</sup>	Kind Co		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T⁵
	F1		NL 1014289		С	Waldinger et al.	08-07-2001	ALL	
	F2	V	O 03/011340		A1	Wohlrab Johannes	02-13-2003	ALL	
	F3	V	VO 99/52517		A2	Sigma Tau Ind. Farmaceuiti.	10-21-1999	ALL	
	F4	v	VO 00/23057	,	A2	Janssen Pharmaceuitica N.V.	04-27-2000	ALL	
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<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>&</sup>lt;sup>1</sup> Unique citation designation number. <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

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Substitute for form 1449B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT

of :

Complete if Known **Application Number** 10/809,631 **Filing Date** March 24, 2004 **First Named Inventor** Nathan Andrew Shapira **Group Art Unit** 1614 **Examiner Name** Unknown **Attorney Docket Number** UF-368XC1

(use as many sheets as necessary)

OTHER PRIOR ART—NON PATENT LITERATURE DOCUMENTS Include name of the author (in CAPITAL LETTERS), title of the article, (when appropriate), title of the Examiner Cite T<sup>2</sup> item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), Initials\* No. publisher, city and/or country where published. KRISTIANSEN, KURT et al, "Molecular modeling of serotonin, ketanserin, ritanserin and their 5-HT receptor interactions," European Journal of Pharmacology (1996), 306:195-210. R1 LE WITT, PETER, "Hyperhidrosis and hypothermia responsive to oxybutynin," Neurology (1988), 38:506-507. R2 LI, JAMES P. et al. "Roles of 5-HT receptors in the release and action of secretion on pancreatic secretion in rats," Am. J. Physiol. (2001), 280:G595-G602. R3 MARCY, R. et al., "Anhidrotic Activity of Anti Choliinergics in Mice use of Different Routes of Administration," Annales de Dermatologie et de Venereologie (1977), 104:500-501. R4 PASQUINI, M. et al., "Mirtazapine for hyperhidrosis," Psychosomatics, United States (2003), 44(5):442-443. R5 POMIER-LAYRARGUES, G. et al., "Combined Treatment of Portal Hypertension with Ritanserin and Propranolol in Conscious and Unrestrained Cirrhotic Rats," Hepatology (1992), 15:878-882. **R6** SAADIA, DANIELA et al., "Botulinum toxin type A in primary palmar hyperhidrosis: Randomized, single-blind, twodose study," Neurology (2001), 57:2095-2099. R7 SCHMIDT, ANNE W. et al., "Ziprasidone: a novel antipsychotic agent with a unique human receptor binding profile," European Journal of Pharmacology (2001), 425:197-201. R8 SEVILLE, R. H. et al., "Treatment of Hyperhidrosis with Topical Propantheline -- a New Technique," British Journal of Dermatology (1972), 86:441. R9 WILLIAMS, F. M. et al., "Pharmacodynamics and pharmacokinetics of single doses of ketanserin and propranolol alone and in combination in healthy volunteers," British Journal of Clinical Pharmacology (1986), 22:301-308. R10 **R11 R12** R13

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<sup>&</sup>lt;sup>1</sup> Unique citation designation number. <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.